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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/928,242	Applicant(s) LOHRAY ET AL.	
	Examiner Sonya Wright	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,13,14,18,19,22-27,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18,19,23,36 and 37* is/are rejected.

7)☒ Claim(s) *2-9,13,14,22 and 24-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9, 13, 14, 18, 19, 11-17, 36, and 37 are pending in this application.

Election/Restrictions

Applicant's election of Group I, claims 1-9, 13, 14, 18, 29, 22-27, and 36-37 with traverse in Paper number 6, filed 9-4-02 has been acknowledged. The traversal is on the grounds that the inventions are appropriately included in a single application as the claims recite interrelated subject matter, which should be the overriding concern in determining the proprietary of the restriction requirement. Further Applicants respectfully assert that examination of these groups of claims in combination would not be unduly prolonged or burdensome.

This is not found persuasive because inventions in Groups I, IV, and VII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful in the preparation of various products and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Inventions in Groups I, V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The process in Group V and the process in Group VI are processes for preparing the same compound. Therefore, the product as claimed can be made by at least one other materially different process.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another and materially different product. See page 4 of the specification, lines 18-28 and figures II and III, pages 5 and 6 in their entirety, and page 7, lines 1-9.

In Group IX, the merit of patentability is on the dosage and kind of specific ingredients and their activity functioning together.

To not restrict this application would create a burden on the Examiner because the Examiner must search classes and subclasses as well as perform an online structure search.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 18, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 1 and 36 are directed to compounds of formula I and their derivatives their analogs, and their polymorphs, carboxylic acid and its derivatives, sulfonic acid and its derivatives, phosphonic acid and its derivatives. The specification does not reasonably provide enablement for the instantly claimed compounds.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. The prior art does not indicate which derivatives, analogs, polymorphs,

derivatives of sulfonic acid and derivatives of phosphonic acid may be useful in the claimed invention. There is little predictability in the art of which modifications may be made to the claimed compound which would retain it's ability to be useful in treating obesity, hyperlipidaemia, and atherosclerosis. The terms derivatives, analogs, and polymorphs, derivatives of sulfonic acid, and derivatives of phosphonic acid may encompass a great number of compounds however, without some guidance as to what changes may be made to the compounds of formula I, there would be little predictability in making and/or using such derivatives, analogs, and polymorphs, derivatives of sulfonic acid, and derivatives of phosphonic acid. The level of ordinary skill in the art is high. The specification fails to provide guidance or any working examples for what derivatives, analogs, and polymorphs, derivatives of sulfonic acid and derivatives of phosphonic acid may be made or used. The skilled artisan would have a numerous amount of modifications to perform in order to obtain derivatives, analogs, and polymorphs, derivatives of sulfonic acid and derivatives of phosphonic acid as claimed, therefore undue experimentation would be required.

Claim 18 is directed to "a method of preventing diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. There are a vast number of diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity,

impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic complications and applicant does not give support for "preventing" all forms of these disorders. The art pertaining to diseases caused by hyperlipidaemia, hypercholesteremia, hyperglycemia, obesity, impaired glucose intolerance, leptin resistance, insulin resistance, (and) diabetic remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

Claim 37 is directed to "converting a compound of formula (I) into a further compound of formula (I)", "resolving the racemic mixture into pure enantiomers by the known methods", and "preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof". The specification does not reasonably provide enablement for the instantly claimed compounds.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. The claims lack positive steps which teach how "converting a compound of formula (I) into a further compound of formula (I)", "resolving the racemic mixture into pure enantiomers by the known methods", and "preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a

pharmaceutically acceptable solvate thereof" are performed. There is little predictability in the art of which modifications may be made to the processes as claimed in order to prepare the claimed compound. The terms "converting a compound of formula (I) into a further compound of formula (I)", "resolving the racemic mixture into pure enantiomers by the known methods", and "preparing a pharmaceutically acceptable salt of a compound of formula (I) and/or a pharmaceutically acceptable solvate thereof" may encompass a great number of processes, however, without some guidance as to how these processes are performed, there would be little predictability in making the invention as claimed. The level of ordinary skill in the art is high. The skilled artisan would have a numerous amount of modifications to perform in the processes as claimed order to obtain the claimed compound, therefore undue experimentation would be required to prepare instant compounds which are useful in the treatment of migraine.

These rejections can be overcome by Applicant deleting the terms derivatives, analogs, and polymorphs in claim 1, deleting the term "preventing" in claim 18, and listing positive process steps in claim 37.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 23, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, line 7, the abbreviation (PCOS) is redundant and is therefore not needed.

In claim 23, the species listings are confusing. For example, the first species listed is (+) 3-{4-[2-(pyrrol-1-yl)ethoxy]phenyl}-2-ethoxypropanoic acid, and following the species name is "and its Li, Na, K, Ca, Mg, lysine, arginine, guanidine and its derivatives". It is requested that Applicant clarify the wording following each species listed in claim 23. For example, it appears that the term "and its derivatives" is not needed or should appear at another place in the claim. Applicant should note that if the term derivative is left in the claim it will be rejected under 35 U.S.C. 112 first paragraph.

The preamble of claim 36 is drawn to a process for the preparation of a compound of formula (I) as claimed in claim 1, . . . which comprises. . ." The preamble suggests that the steps are all steps comprised in one process. However, each step is a different process of preparing a compound of formula (I). Therefore, the preamble is confusing. Appropriate correction is requested.

Claim 37 is drawn to a process of converting a compound of formula (I) into a further compound of formula (I). It is unclear what is meant by the phrase "a further compound of formula (I)". For example, is "a further compound of formula (I) an additional compound of formula (I)? Is "a further compound of formula (i) a modified compound of formula (I)? Appropriate correction is requested.

Also, claim 37 contains the term "and/or" in step iv, which is confusing. It is unclear whether or not a pharmaceutically acceptable solvate is prepared with a

pharmaceutically acceptable salt. It is suggested that Applicant delete "and/or" and insert "and optionally".

Claim Objections

Claim 36 is objected to because of the following informalities: Claim 36 depends from canceled claims in steps b, c, d, e, and f. Appropriate correction is required.

Claims 2-9, 13, 14, 22 and 24-27 are objected to for being dependent on a rejected claim.

The reference cited on the PTO-892 is cited only to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the

applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Joseph K. McKane

Supervisory Patent Examiner

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Sonya Wright

November 23, 2002